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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/588,377 | 02/07/2007 | Marta Guerrero | 2294-0119PUS1 | 8434 |

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| EXAMINER | |
|---|---|
| YEAGER, RAYMOND P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1619 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 06/03/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/588,377 | GUERRERO ET AL. | |
| | Examiner | Art Unit | |
| | RAYMOND P. YEAGER | 1619 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Application 10/588,377 (02/07/2007) is a national stage entry of PCT/EP05/01038 (02/02/2005) per 35 USC 371 and claims foreign priority to EPO 04002317.8 (02/03/2004) per 35 USC. Claims 1 to 24 are pending.

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### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 1 to 23 are drawn to *a pharmaceutical composition*.

Group II, claim 24 is drawn to *a process for preparing a pharmaceutical composition*.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to forma single general inventive concept." Moreover, as stated in PCT rule 13.2, "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art"

3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Group I is a *pharmaceutical composition comprising a statin and an antiflatulent agent*. The *pharmaceutical composition comprising a statin and an antiflatulent agent* claim 1 does not present a contribution

over the prior art. As disclosed in US Patent 6,534,088 (Publication date: 03/18/2003; Filing date: 04/20/2001), hereafter referred to as the '088 patent, in view of Davidson et al, 2002, and Abu-Yousef and El-Zein, 2000, the *pharmaceutical composition comprising a statin and an antiflatulent agent* of instant claim 1 lacks an inventive step.

**Instant claim 1**: "*A pharmaceutical composition comprising a statin and an antiflatulent agent in a suitable proportion as an active ingredient*." – The '088 patent discloses atorvastatin formulated with pharmaceutically acceptable excipients which include simethicone ('088, column 3, lines 43-57). The prior art teachings of the '088 patent differ from the claimed invention as follows: Though one of ordinary skill in the art at the time the invention was made could readily envision an atorvastatin and simethicone formulation, the '088 patent does not explicitly provide this embodiment. However, the combination of Davidson et al, 2002 and Abu-Yousef and El-Zein, 2000 teach all the limitations that are deficient in the '088 patent: Abu-Yousef and El-Zein, 2000 teach that one of the most frequent side effects for atorvastatin is flatulence (page 271, column 2, safety section, lines 8-10). Davidson et al, 2002 teaches simethicone is a well-known emulsifying agent that has been used previously in upper gastrointestinal examinations to break down large pockets of gas by changing their surface tension (last 3 lines on the page 780). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine a statin (i.e. atorvastatin) the simethicone pharmaceutical excipient of the '088 patent because the combination of Davidson et al, 2003 and Abu-Yousef and El-Zein, 2000 teach that the flatulence problem associated with atorvastatin can be treated with simethicone as discussed *supra*. A person of ordinary skill in the art would have been motivated to do so because Abu-Yousef and El-Zein, 2000 teach that the use of simethicone is simple, inexpensive, safe, and effective (page 785, column 2, lines 6-12). A person of ordinary skill in the art would reasonably have expected to be successful because Abu-Yousef and El-Zein, 2000 teach that there were no side effects such as those normally associated with a cellulose based agent (page 784, column 1, lines 12).

As such, Group I does not share a special technical feature with the instant claims of Group II. Therefore, the claims are not so linked with the meaning of PCT

Rule 13.2 so as to form a single inventive concept, and unity between Groups I-II is broken.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Election of Species***

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. The applicant must elect the following species:

- If applicant elects Group I, the following species elections are required:
  - One specific *pharmaceutical composition* defining one compound for each component. Applicant must elect:
    - One specific *diluent*;
    - One specific *binder*;
    - One specific *disintegrant*;
    - One specific *lubricant*;
    - IF present, one specific *antioxidant*;
    - IF present, one specific *wetting agent*;
    - IF present, one specific *coating;*
    - IF present, one specific *colouring agent*;
- If applicant elects Group II, the following species elections are required:
  - One specific *pharmaceutical composition* defining one compound for each component. Applicant must elect:
    - One specific *diluent*;
    - One specific *binder*;
    - One specific *disintegrant*;
    - One specific *lubricant*;
    - IF present, one specific *antioxidant*;
    - IF present, one specific *wetting agent*;
    - IF present, one specific *coating;*
    - IF present, one specific *colouring agent*;

Specifically, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon Applicant's election of species, the result must provide a single chemical species and a single condition or disease to be treated or improved. The reply must also

identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, one specific *pharmaceutical composition* as defined above for group I and one specific *pharmaceutical composition* as defined above for group II, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic for group I and no claims generic for group II.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding technical feature for the following reasons: As discussed *supra*.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitation of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Fri 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615